

## **DETAILED ACTION**

### ***Response to Arguments***

Applicants present arguments over the 35 USC 103 rejection of Ueda et al. in view of Hamilton. In particular, it is argued that the Ueda reference is directed to a theanine-containing composition for suppressing and ameliorating many symptoms that are not recited in the present claims. It is argued that even if symptoms associated with feelings of guilt, suicide, and retardation: psychomotor are disclosed in Ueda, the method of the present invention is only specifically directed to treating the main symptoms and not any associated symptoms.

In response to the above arguments, it is noted that Ueda et al. does not specifically use the words “feelings of guilt, suicide and retardation:psychomotor” when describing symptoms. However, Ueda et al. teaches symptoms that overlap with those listed in claim 5. Ueda et al. discusses the treatment of anxiogenic symptoms that can be associated with diminished homeostasis of which symptoms of diminished homeostasis include spiritlessness, aggressiveness, faintheartedness, maudliness and psychological lift. Ueda et al. teaches symptoms that overlap with the present claims, for example, anxiogenic symptoms are often indicated in feelings of guilt and suicide. Theanine will treat the symptoms regardless of the etiology. Regarding Applicants argument that the method of the present invention is only specifically treating the main symptoms and not any associated symptoms, the claim is drawn to treating the claimed symptoms, which is associated with a mood disorder. Therefore, the symptoms are associated and regardless of if the symptoms are main symptoms or associated

symptoms, if the treatment will treat the symptom it will regardless of how the symptom is defined.

Please see the modified rejection below due to Applicant's amendments.

***Claim Rejections – 35 U.S.C. § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5, 7 and 13-14 rejected under 35 U.S.C. 103(a) as being unpatentable over Ueda et al. (U.S. Patent 6,831,103) in view of Hamilton (J Neurol Neurosurg Psychiat, 1960, 23, 56).

Ueda et al. teaches the administration of a theanine-containing composition that is capable of ameliorating symptoms such as anxiogenic symptoms that include those symptoms due to an unidentified cause and associated with diminished homeostasis (Col. 1, lines 13-22; Col. 4, lines 41-61 and Test Example 3). Further, diminished homeostasis is a disorder that falls under the broad term of mood disorder as claimed and is treated with theanine and further symptoms of diminished homeostasis include spiritlessness, aggressiveness, faintheartedness, maudliness and psychological lift. Further, Ueda et al. teaches that diminished homeostasis is a state wherein stably maintaining morphological and physiological conditions in normal ranges in altered and

this includes changes in nervous system regulation (Col. 3, lines 60 – Col. 4, lines 1-6). Ueda et al. further teach that theanine may be contained in different types of food or beverages (Col. 6, lines 8-67 – Col. 7, lines 1-17). Ueda et al. teaches that the content of theanine in the composition is preferably from 0.005 to 100% by weight, which overlaps with the amounts in new claim 14. Ueda et al. is silent as to whether the patient is normofolatemic or not. However, absence a showing of criticality that the product shows unexpected results in normofolatemic patients, the invention is deemed obvious over Ueda et al. Ueda et al. does not specify that the symptoms of mood disorder as feelings of guilt, suicide and retardation:psychomotor; however, Ueda et al. generally teaches treating symptoms of mood disorder which would include all of these symptoms. Primarily anxiogenic symptoms are often indicated in feelings of guilt and suicide. Further diminished homeostasis symptoms read on the symptoms of retardation:psychomotor. Accordingly, Ueda et al. teaches treating mood symptoms which render the present invention obvious.

Ueda et al. do not specifically teach that the mood is assessed by the Hamilton scale.

Hamilton teaches a rating scale for measuring symptoms of mental disorder, including the symptoms such as feelings of guilt, suicide, retardation:psychomotor and diminished insight (see whole document).

Accordingly, it would be obvious to a person of ordinary skill in the art at the time of the invention that the Hamilton scale would be an effective assessment of symptoms associated with mood disorders because of the teachings of Ueda et al. that theanine

containing compositions are effective in treating various symptoms of mood, particularly those associated with anxiety and diminished homeostasis. It would further be obvious that the rating scale, or score, for the treated symptoms would be decreased on the Hamilton Scale after treatment with theanine. One would be motivated to use the Hamilton scale because it is a scale commonly used to assess various mood disorders, including depressed states. Therefore, the other factors in the scale would also be measured.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is (571)272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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